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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,681

09/19/2007

Yoshio Koga

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10/08/2010

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EXAMINER

KOSTELNIK, SUMMER LEIGH

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

10/08/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,681	<b>Applicant(s)</b> KOGA ET AL.	
	<b>Examiner</b> SUMMER L. KOSTELNIK	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/28/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Drawings***

The drawings are objected to because they are labeled in Japanese. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the computer has a planning assistance function and an

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intraoperative function or the assisting terminal. It is also unclear what is meant by "supports a total knee joint replacement," a "function of acquiring," and a function of determining a bone resection margin." Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia, III et al., Pat. No. US 6,205,411 B1 in view of McQueen et al., Pat. No. US 5,108,398 in further view of Ferrante et al., Pat. No. US 5,275,603.

Regarding claim 9, DiGioia, III et al. discloses a total knee joint replacement assisting terminal which uses a computer, has a planning assistance function before an intervention (Fig. 2) and an intraoperative assistance function (Fig. 2), and supports a total knee joint replacement (abstract). DiGioia, III et al. also discloses wherein the intraoperative assistance function includes: a function of acquiring, by a C-arm fluoroscopic apparatus (Fig. 3), a radiographic image data of the intra-medullary rod inserted into a tibia (Fig. 2); a function of acquiring, on the fluoroscopic image obtained by the fluoroscopic apparatus (Fig. 2), rotational position information of the intra-medullary rod in a medullary cavity put of the position of an intersection of a pair of wires of the intra-medullary rod (Fig. 2); and a function of determining a bone resection margin using the intra-medullary rod as a reference anatomical axis (Fig. 2); and wherein an anterior articular surface of the femur is determined perpendicularly to a load shaft

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from an angle with the femoral load shaft determined using the planning before the intervention, and a resected bone surface is determined (Figs. 1 and 2).

However, DiGioia, III et al. does not disclose a bone cutting positioning jig. Ferrante et al., discloses a bone cutting positioning jig wherein the bone cutting positioning jig comprises a bone cutting direction indicator having a base (26), a universal joint being movably and rotatably supported around three axes to the base of the bone cutting direction indicator through a ball joint (col. 3, lines 44-61) and having a direction indicating jig (col. 3, lines 44-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a bone positioning jig with the total knee joint replacement terminal in order to provide a total system for knee repair, thereby decreasing costs increasing operating room efficiency.

Further, DiGioria, III et al., does not disclose an intra-medullary rod, however McQueen discloses wherein the intra-medullary rod (10) comprises a plurality of wires, which are made of a material that does not transmit X-ray and are deposited at regular intervals along a surface of the cylindrical body in the circumferential direction (col. 5, lines 10-18), being extended in an axial direction in a spiral shape; wherein each of the wires is made in a way that a starting end and a terminating end of the cylindrical body are connected by the shortest distance along the outer surface thereof (col. 5, lines 35-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an intra-medullary rod with the total knee joint replacement terminal in order to provide a total system for knee repair, thereby decreasing costs and increasing operating room efficiency.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUMMER L. KOSTELNIK whose telephone number is (571)270-5339. The examiner can normally be reached on M-F 7:30-5:00, 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. L. K./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

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